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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,356	06/03/2005	Klaus Dietzel	26794U	2653

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EXAMINER	
JEAN-LOUIS, SAMIRA JM	
ART UNIT	PAPER NUMBER
1617	
MAIL DATE	DELIVERY MODE
05/22/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/537,356	DIETZEL ET AL.	
	Examiner	Art Unit	
	SAMIRA JEAN-LOUIS	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 February 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-11 and 13-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-11 and 13-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continuation Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02/20/09 has been entered.

Response to Arguments

This Office Action is in response to the amendment submitted on 02/20/2009. Claims 6-11 and 13-17 are pending in the applications, with claims 1-5, 12, and 18-23 having being cancelled. Accordingly, claims 6-11 and 13-17 are being examined on the merits herein.

Receipt of the aforementioned amended claims is acknowledged and has been entered.

Applicant's argument that a proper case of *prima facie* has not been established because whether taken alone or together, none of the cited references (i.e. Magee in view of Calatayud) suggest all the limitations of the claims has been fully considered but is not found persuasive. Applicant further argues that the present claims recite a pharmaceutical fixed combination of formoterol and ciclesonide which are ready mixed

and which is not taught by the prior art. Again, such arguments are not persuasive as the features upon which applicant relies (i.e., fixed combination or ready mixed in a fixed combination) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Moreover, regardless of the newly added claim limitations, Magee in view of Calatayud still render obvious applicant's invention. Magee clearly teaches the use of ciclesonide in conjunction with formoterol for the treatment of several diseases including bronchitis, COPD, and asthma which are all airway diseases. Magee further teaches that the composition can be formulated by nasal aerosol or inhalation forms. Importantly, Magee teaches that the compounds and therapeutic agents can be administered in combination wherein the compounds or components are formulated together (i.e. fixed combination and necessarily ready mixed) into a single dosage form which releases the components and compounds at substantially the same time (see pg. 92, paragraph 0572). Calatayud, on the other hand, was provided to demonstrate that the R-epimer of formoterol is highly effective in pharmacological activity and possess minimal systemic effects. As a result, the Examiner contends that Magee in view of Calatayud et al. do indeed render obvious applicant's invention. Thus, the rejections of record were indeed proper.

Applicant's argument that a proper case of *prima facie* has not been established because whether taken alone or together, none of the cited references (i.e. Keller in

view of Calatayud) suggest all the limitations of the claims has been fully considered but is not found persuasive. Applicant further argues that the present claims recite a pharmaceutical fixed combination of formoterol and ciclesonide which are ready mixed and which is not taught by the prior art. Again, such arguments are not persuasive as the features upon which applicant relies (i.e., fixed combination or ready mixed in a fixed combination) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). As for applicant's arguments that Keller et al. doe not teach the use of R, R, formoterol, such arguments are again not found persuasive as Keller et al. particularly teach a formulation additionally containing ciclesonide in combination with formoterol tartrate or tartrate (see col. 7, lines 5-10). Moreover, regardless of the newly added claim limitations, Keller in view of Calatayud still renders obvious applicant's invention. Keller et al. teach dry powder formulations which contain a beta mimetic in the form of salt such as formoterol fumarate or formoterol tartrate (instant claims 9-10), and/or an anticholinergic and/or a corticosteroid including ciclesonide. Again, Calatayud et al. was provided to demonstrate that the R-epimer of formoterol is highly effective in pharmacological activity and possess minimal systemic effects. As a result, the Examiner contends that Keller in view of Magee and in further view of Calatayud et al. did indeed render obvious applicant's invention. Thus, the rejections of record were indeed proper.

For the foregoing reasons, the rejections of record were indeed proper. However, in view of applicant's amendment, the rejections of record are withdrawn and the following modified 112, first paragraph and 103 (a) Non-Final rejections are being made.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6-11 and 13-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a pharmaceutical composition and/or a method of treating an airway disease comprising the active compound ciclesonide, epimer, and the active compound R,R-formoterol, salt, hydrate salt, in fixed combination and in an administration form suitable for inhalative administration by means of a powder inhaler wherein the active compound ciclesonide, epimer and the active compound R,R-formoterol, or a hydrate of a salt are present ready mixed in a fixed combination, does not reasonably provide enablement for such pharmaceutical composition and/or method of treating an airway disease comprising the solvate, physiologically functional derivative, or the solvate of the physiologically functional derivative of ciclesonide along with the solvate, hydrate, solvate of a salt of R,R-formoterol. The specification does not enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The instant claims are drawn to a pharmaceutical composition and/or a method of treating an airway disease comprising the active compound ciclesonide, solvate, epimer, physiological functional derivative or a solvate of a physiologically functional derivative and the active compound R,R-formoterol, salt, hydrate, solvate, hydrate of a salt, or solvate of a salt thereof, in fixed combination and in an administration form suitable for inhalative administration by means of a powder inhaler wherein the active compound ciclesonide, solvate, epimer, physiological functional derivative or a solvate of a physiologically functional derivative and the active compound R,R-formoterol, salt, hydrate, solvate, hydrate of a salt, or solvate of a salt thereof are present ready mixed in a fixed combination. The instant specification fails to provide information that would allow the skilled artisan to practice the treatment of an airway disease or formulate a composition containing the solvate, physiologically functional derivative, or the solvate of the physiologically functional derivative of ciclesonide along with the solvate, hydrate, solvate of a salt of R,R-formoterol.

In re Sichert, 196 USPQ 209 (CCPA 1977)

To be enabling, the specification of the patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. In re Wright, 999 F.2d 1557, 1561 (Fed. Cir. 1993). Explaining what is

meant by "undue experimentation," the Federal Circuit has stated:

> The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the claimed invention. PPG v. Guardian, 75 F.3d 1558, 1564 (Fed. Cir. 1996).[1]

The factors that may be considered in determining whether a disclosure would require undue experimentation are set forth by In re Wands, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,
2) the amount of direction or guidance provided,
3) the presence or absence of working examples,
4) the nature of the invention,
5) the state of the prior art,
6) the relative skill of those in the art,
7) the predictability of the art, and
8) the breadth of the claims.

These factors are always applied against the background understanding that scope of enablement varies inversely with the degree of unpredictability involved. In re Fisher, 57 CCPA 1099, 1108, 427 F.2d 833, 839, 166 USPQ 18, 24 (1970). Keeping that in mind, the Wands factors are relevant to the instant fact situation for the following reasons:

1. The nature of the invention, state and predictability of the art, and relative

[1] As pointed out by the court in In re Angstadt, 537 F.2d 498 at 504 (CCPA 1976), the key word is "undue", not "experimentation".

skill level

The invention relates to a pharmaceutical composition and/or a method of treating an airway disease comprising the active compound ciclesonide, solvate, epimer, physiological functional derivative or a solvate of a physiologically functional derivative and the active compound R,R-formoterol, salt, hydrate, solvate, hydrate of a salt, or solvate of a salt thereof, in fixed combination and in an administration form suitable for inhalative administration by means of a powder inhaler wherein the active compound ciclesonide, solvate, epimer, physiological functional derivative or a solvate of a physiologically functional derivative and the active compound R,R-formoterol, salt, hydrate, solvate, hydrate of a salt, or solvate of a salt thereof are present ready mixed in a fixed combination. The relative skill of those in the art is high, that of an MD or PHD. That factor is outweighed, however, by the unpredictable nature of the art. As illustrative of the state of the art, the examiner cites Vippagunta et al. who teach predicting the formation of solvates or hydrates of a compound and the number of molecules of water or solvent incorporated into the crystal lattice is both complex and difficult. All compounds respond differently to possible formation of hydrates. Consequently, Vippagunta et al. teach that generalizations cannot be made for a series of compounds and their respective solvates (see Vippagunta et al., Advanced Drug Delivery Reviews, 2001, Vol. 48, pg. 18, section 3.4) and applicant fails to provide enablement support.

2. The breadth of the claims

The claims are thus very broad insofar as they recite a pharmaceutical composition and/or a method of treating an airway disease comprising the active compound ciclesonide, solvate, epimer, physiological functional derivative or a solvate of a physiologically functional derivative and the active compound R,R-formoterol, salt, hydrate, solvate, hydrate of a salt, or solvate of a salt thereof, in fixed combination and in an administration form suitable for inhalative administration by means of a powder inhaler wherein the active compound ciclesonide, solvate, epimer, physiological functional derivative or a solvate of a physiologically functional derivative and the active compound R,R-formoterol, salt, hydrate, solvate, hydrate of a salt, or solvate of a salt thereof are present ready mixed in a fixed combination, yet applicant fails to provide enablement on how the synthesis of ciclesonide solvate, physiologically functional derivative of ciclesonide (i.e. other than 21-hydroxy derivative of ciclesonide), solvate of a physiologically functional derivative of ciclesonide along with the hydrate of R,R-formoterol, solvate of formoterol, or the solvate of a salt of formoterol will be accomplished as previously mentioned.

3. The amount of direction or guidance provided and the presence or absence of working examples

The specification is not adequately enabled as to how to make ciclesonide solvate, physiologically functional derivative of ciclesonide (i.e. other than 21-hydroxy derivative of ciclesonide), solvate of a physiologically functional derivative of ciclesonide

along with the hydrate of R,R-formoterol, solvate of formoterol, or the solvate of a salt of formoterol and provides no direction or guidance for a method to synthesize the aforementioned compounds. In fact, applicant provided no guidance on how to obtain the aforementioned compounds except the physiologically functional 21-hydroxy derivative of ciclesonide. As a result, countless experimentation would be necessary to obtain the ciclesonide solvates, all other physiologically functional derivatives of ciclesonide, solvates of a physiologically functional derivative of ciclesonide along with the hydrates of R,R-formoterol, solvates of formoterol, or the solvates of salts of formoterol claimed by applicant.

4. The quantity of experimentation necessary

Because of the known unpredictability of the art, and in the absence of experimental evidence, no one skilled in the art would accept the assertion that the instantly claimed solvates, physiologically functional derivatives, and solvates of physiologically functional derivatives of ciclesonide and the hydrates, solvates, or solvates of salts of R,R-formoterol could be predictably made as inferred by the claim and contemplated by the specification. Accordingly, the instant claims do not comply with the enablement requirement of §112, since to practice the invention claimed in the patent a person of ordinary skill in the art would have to engage in undue experimentation in order to obtain the solvates, hydrates, physiologically functional derivatives, solvates of salts, solvates of physiologically functional derivatives of the aforementioned compounds claimed by applicant, with no assurance of success.

Genentech, 108 F.3d at 1366 states that " a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Thus, in the absence of working examples there is no showing that the instant compounds will form solvates, hydrates, physiologically functional derivatives, solvates of salts, or solvates of physiologically functional derivatives. Since it is clear that merely bringing the compound into contact with water or a solvent does not result in a hydrate, additional direction or guidance is needed to make them and the specification has no such direction or guidance. Therefore, only the chemically structurally defined chemicals, but not the full breadth of the claims meet the enablement requirement provision of 35 USC § 112, first paragraph.

Therefore, a pharmaceutical composition and/or a method of treating an airway disease comprising the active compound ciclesonide, solvate, epimer, physiological functional derivative or a solvate of a physiologically functional derivative and the active compound R,R-formoterol, salt, hydrate, solvate, hydrate of a salt, or solvate of a salt thereof, in fixed combination and in an administration form suitable for inhalative administration by means of a powder inhaler wherein the active compound ciclesonide, solvate, epimer, physiological functional derivative or a solvate of a physiologically functional derivative and the active compound R,R-formoterol, salt, hydrate, solvate, hydrate of a salt, or solvate of a salt thereof are present ready mixed in a fixed combination is not considered to be enabled by the instant specification.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 6-11 and 13-17 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Magee et al. (2002/0111495 A1, previously submitted) in view of Calatayud et al. (U.S. 5,482,934, previously submitted).

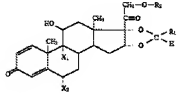
This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Magee et al. teach compounds of formula I useful as inhibitors of PDE4 in the treatment of diseases especially asthma, chronic bronchitis, and chronic obstructive pulmonary disease (abstract and pg. 1, paragraph 0006). Magee et al. further teach that the compounds may be made in a composition together with a pharmaceutical carrier for treating a number of diseases including bronchitis, obstructive bronchitis, COPD, allergic asthma and bronchial asthma (instant claims 11 and 15; see pg. 32, paragraphs 0190-0194). Magee et al. further teach the combination of a compound of formula I together with one or more therapeutic agents including formoterol and ciclesonide (instant claim 6; see pg. 34, paragraph 0218, and pg. 98, paragraphs 0620, 0630, and 0636). These compounds and therapeutic agents are administered to a patient in combination with the compounds of formula I wherein the compounds or components are formulated together (i.e. fixed combination and this necessarily meets the limitation of ready mixed as they are formulated as a single dosage unit) into a single dosage form which releases the components and compounds at substantially the same time (instant claims 6 and 11; see pg. 92, paragraphs 0571-0572 and pg. 99, paragraph 0671). The compounds and therapeutic agents according to Magee et al. may be in the form of salts or acid salts including acetate, citrate, fumarate, gluconate, hydrochloride, hydrobromide, nitrate, sodium phosphate, stearate, sulfate, sulfosalicylate and tartrate (instant claims 9-10; see pg. 99-100, paragraphs 0672, 0674 and 0676) and may be administered in various dosages and follow various treatment regimen depending upon a variety of factors including drug combination, age, body weight, general health, sex, diet, time of administration, rate of excretion, physician's

judgment and severity of the disease (instant claims 11, 16-17; see pg. 99, paragraph 0671). Finally, Magee et al. teach that the pharmaceutical composition may be administered by nasal aerosol or inhalation through the use of a dry powder inhaler (instant claims 6, 11 and 14; see pg. 104, paragraphs 0709 and 0719).

Magee et al. do not specifically teach the R-epimer of ciclesonide in an amount greater than 95% in the pharmaceutical composition.

Calatayud et al. teaches compounds of the general formula



with X1 an X2 corresponding to H and R1 is a phenyl group and R2 represents radicals such as C=OCH(CH3)CH3 in the form of an R epimer, S epimer or mixture of the R and S epimers (i.e. ciclesonide) as drugs and/or therapeutic agents (see abstract and col. 3, lines 1-61). Calatayud et al. further teach that these compounds possess intense pharmacological activity with no or minimal systemic effects (see col. 2 lines 21-23, col. 15, lines 10-11 and col. 16, lines 27-30). Calatayud et al. also teach synthesis of the mixture of ciclesonide with both the R and S epimers which are then further purified to obtain either of the epimers in a proportion of at least 99.9% (see col. 11, lines 21-61 and col. 17-18, table II, compound 9). Importantly, Calatayud et al. teach that the R-epimer of ciclesonide possesses high anti-inflammatory activity, high glucocorticoid activity and high therapeutic index (see col. 17-18, table 3 compound 9).

Thus, to one of ordinary skill in the art at the time of the invention would have found it obvious to utilize the R-epimer of Calatayud into the composition of Magee et al. to treat airway diseases since Calatayud et al. teach that the R-epimer possesses intense glucocorticoid activity with minimal systemic effects. Given that Magee et al. teach a pharmaceutical composition comprising compounds of formula I together with ciclesonide and formoterol, and Calatayud et al. teach R-epimers of ciclesonide with high glucocorticoid activity, anti-inflammatory activity and minimal systemic effects, one of ordinary skill would have been motivated to incorporate the R-epimer of ciclesonide into the composition of Magee et al. with the reasonable expectation of providing a pharmaceutical composition that is efficacious in treating airway diseases and a composition that is readily absorbed with no systemic effects.

Claims 6-11 and 13-17 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Keller et al. (U.S. 6,645,466 B1, previously submitted) in view of Magee et al. (2002/0111495 A1, previously submitted) and in further view of Calatayud et al. (U.S. 5,482,934, previously submitted).

The Magee and Calatayud references are as discussed above and incorporated by reference herein.

Keller et al. teach dry powder formulations for inhalation (i.e. instant claim 6) containing a pharmaceutically effective carrier, pharmaceutically active compounds and

magnesium stearate (see abstract and col. 4, lines 55-67). Keller et al. further teach that the magnesium stearate is added to dry powder formulations which contain a beta mimetic in the form of salt such as formoterol fumarate or formoterol tartrate (instant claims 9-10), and/or an anticholinergic and/or a corticosteroid including ciclesonide (instant claim 6; see col. 6, lines 52-64 and col. 7, lines 5-10). The amount of active compounds in the formulations can vary within wide ranges or from 0.1-10% though the exact volumetric dosage can be determined depending on the desired dose (instant claim 16; see col. 7, lines 12-39). Additionally, Keller et al. teach that the magnesium stearate which is added to the composition helps improve resistance to moisture and is present along with the therapeutic compounds in the form of interactive mixtures (i.e. ready mixed; see col. 2, lines 5-8; col. 4, lines 62-65 and col. 5, lines 1-8). Keller further teaches single dosage administration wherein the magnesium stearate is mixed together with the active ingredients in any desired sequence or wherein the magnesium stearate mixed separately and then the active compounds are admixed in the magnesium stearate mixture (see col. 8, lines 46-65).

Keller et al. do not specifically teach a method of treating airway diseases or the addition of the R-epimer of ciclesonide into the composition.

As previously stated, Magee et al. teach pharmaceutical composition for the treatment of airway diseases including asthma and COPD containing compounds of formula I along with ciclesonide and formoterol where they are administered together

(i.e. fixed combination and this necessarily meets the limitation of ready mixed as they are formulated as a single dosage unit) into a single dosage form which releases the components and compounds at substantially the same time (instant claims 6, 11, and 15; see pg. 92, paragraphs 0571-0572 and pg. 99, paragraph 0671). Moreover, Magee et al., also teach that these agents may be administered in various dosages and follow various treatment regimen depending upon a variety of factors (instant claims 11, 16-17; see pg. 99, paragraph 0671).

Calatayud et al. teach synthesis of the mixture of ciclesonide with both the R and S epimers and which are then further purified to obtain either of the epimers in a proportion of at least 99.9% (see col. 11, lines 21-61 and col. 17-18, table II, compound 9). Importantly, Calatayud et al. teach that the R-epimer of ciclesonide possesses high anti-inflammatory activity, high glucocorticoid activity and high therapeutic index (see col. 17-18, table 3 compound 9).

Thus, to one of ordinary skill in the art at the time of the invention would have found it obvious to substitute the R-epimer of Calatayud et al. into the composition of Keller et al. since Calatayud et al. teach that the R-epimer of ciclesonide possesses high anti-inflammatory activities. Likewise, it would have been obvious to one of ordinary skill in the art at the time of the invention to vary the treatment regimen as taught by Magee et al. and use the aforementioned composition for the treatment of airway diseases since Magee et al. teach the same type of composition for the

treatment of asthma and COPD. Given that Keller teaches dry powder inhaler moisture-resistant compositions containing ciclesonide and formoterol or their salts, and Magee et al. teach pharmaceutical composition containing compounds of formula I along with ciclesonide and formoterol for the treatment of airway diseases including asthma and COPD, and Calatayud et al. teach R-epimers of ciclesonide with high glucocorticoid activity, anti-inflammatory activity and minimal systemic effects, one of ordinary skill would have been motivated to incorporate the R-epimer of ciclesonide into the composition of Keller et al. and further used such composition for the treatment of airway diseases as taught by Magee et al. with the reasonable expectation of providing a pharmaceutical composition that is efficacious in treating asthma and COPD and a composition that produces no systemic effects.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samira Jean-Louis whose telephone number is 571-270-3503. The examiner can normally be reached on 7:30-6 PM EST M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. J. L. /

Examiner, Art Unit 1617

05/11/2009

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617